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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,987	03/05/2002	Robert B. Dickson	P 0280712 DIRO421009	4488

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EXAMINER	
UNGAR, SUSAN NMN	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 09/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/087,987	DICKSON ET AL.	
	Examiner	Art Unit	
	Susan Ungar	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *11 July 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *34-50* is/are pending in the application.

4a) Of the above claim(s) *37* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) *34-36, 38-50* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

S.d.O

1. The Reply to the Notice of Non-Compliant Amendment filed July 11, 2005 in response to the Letter mailed June 16, 2005 is acknowledged and has been entered. The Election filed March 21, 2005, in response to the Office Action mailed October 20, 2004 is acknowledged and has been entered. Claims 1-33 have been canceled and new claims 34-50 have been added. Thus, claims 34-50 are pending in the application and Claim 37 and limitations drawn to premalignant lesions have been withdrawn from further consideration by the examiner under 37 CFR 1.142(b) as being drawn to non-elected inventions. Claims 34-36, 38-50 as they are drawn to direct blockade of matriptase activity, as they are drawn to malignant cancer as well as claim 41 as it is drawn to M69 are currently being prosecuted.

2. Applicant's election with traverse of Group 10, claims 16, 17, 20-22, and the species of M69, in the paper submitted March 21, 2005 is acknowledged. The traversal is on the ground(s) that the inventions the inventions drawn to blocking maltriptase activity in an epithelial tissue and in a non-epithelial tissue is not distinct. Upon review and reconsideration, the restriction between inventions drawn to blocking maltriptase activity in epithelial tissue and in non-epithelial tissue is hereby withdrawn and thus Group 11 is hereby rejoined to Group 10.

Applicant further traverses the requirement for election between the disclosed antibodies M69 and M123. Applicant argues that the application discloses that it is possible to prepare antibodies that are capable of binding specifically to an active form of matriptase without recognizing the inactive form of matriptase and Applicant has prepared and three such antibodies, of which two are instantly claimed. Thus the application enables persons of skill to make, identify and use antibodies other than the two claimed and the search that is

required to identify prior art relevant to practicing the elected inventions is not undue. The argument has been considered but has not been found persuasive, the restriction is not based on whether the invention is enabled. The restriction is based on the finding that the two antibodies are distinct, that is that they have different structures and therefore different functions. Further, the literature search, particularly relevant in this art, is not coextensive and different searches and issues are involved in the examination of each group. Given that the searches are not coextensive, the burden is undue.

Applicant further traverses the requirement for election between examination of malignant and premalignant lesions. Applicant argues that persons of skill in the art recognize that pre-malignant and malignant lesions represent states on a common continuum constituting the accumulation of genetic and biochemical alterations that are characteristic of cancer development, thus the search for both inventions would not be an undue burden. The argument has been considered but has not been found persuasive because different searches and issues are involved in the examination of each group and which represents an undue burden on the Examiner. For these reasons the restriction requirement is deemed to be proper and is therefore made FINAL.

Finally, Applicant requests that upon allowance of the linking claim, that the restriction requirement between Groups 10-13 be withdrawn. Examiner is happy to comply with Applicant's request upon allowance of the linking claim.

3. Upon review and reconsideration and in view of the newly added claims, the inventions of claims 34-36, 38-50 are further subject to restriction.

4. It is noted that the claims of the instant application has been determined to include linking claims The restriction requirement among the linked inventions is

subject to the nonallowance of the linking claim(s), claims 34. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Group 1. Claims 34-36, 38-44, 48-50 drawn to a method of identifying cancer, *in vitro*, comprising active matriptase and upon detecting said active matriptase in a sample, treating said cancer with an antibody/labeled antibody, classified in class 424, subclass 130.1.

Group 2. Claims 34, 45-46 drawn to a method of identifying cancer, *in vitro*, comprising active matriptase and upon detecting said active matriptase in a sample, exposing the same sample to antibodies that recognize inactive matriptase and determining the ratio of the amount of activated matriptase/inactivated matriptase and then treating said cancer with an agent, classified in class 424, subclass 130.1.

Group 3. Claims 34, 47 drawn to a method of identifying cancer, *in vitro*, comprising active matriptase and upon detecting said active matriptase in a sample, the method further comprising detecting and measuring the

concentration of matriptase cognate inhibitor HAI-l and then treating said cancer with an agent, classified in class 424, subclass 130.1.

5. The inventions are distinct, each from the other because of the following reasons:

Inventions 1-3 are materially distinct methods which differ at least in objectives, method steps, reagents used, schedules used, response variables, and criteria for success. For Example Group 1 is drawn to a method of identifying active matriptase and then treating a cancer, while Group 2 is drawn to a method of not only identifying active matriptase but also determining the ratios of active and inactive matriptase, apparently in order to determine whether or not to use the claimed "agent" and Group 3 is drawn not only to a method of identifying active matriptase and then treating a cancer, but is also drawn to a method for detecting and measuring concentration of HAI-1, apparently also to determine whether or not to use the claimed "agent", each of which is a distinct method with different objectives, reagents used, schedules used, response variables, method steps used and criteria for success. Searching the groups with all of the different objectives, reagents, schedules, objectives and steps would invoke a high burden of search.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matter, restriction for examination purposes as indicated is proper.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship

must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

9. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (571) 272-0837. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at (571) 308-0787. The fax phone number for this Art Unit is (571) 273-8300.

Susan Ungar, PhD
Primary Patent Examiner
September 7, 2005